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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/326,502	06/04/1999	STEWART M. KROLL	COUL-005/04U	4274

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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/326,502

Applicant(s)

KROLL ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-20,22-24 and 83-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-20,22-24 and 83-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 8 March 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 2, 4-20, 22-24, and 83-86 are currently pending.

The rejection under 35 USC 103 has been withdrawn in view of Applicant's response.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19 and 84 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 19 and 84 are directed to a dose, which is a variable. A dose will change from patient to patient and from radiopharmaceutical to radiopharmaceutical. Therefore it is not a constant. It is not a process, machine, manufacture, composition of matter, or improvement thereof as required under 35 USC 101 for statutory subject matter.

Note: Claim 84 apparently does recite an intended product, but the claim is still directed to a dosage. Applicant is directed to the 112, 2nd paragraph rejection below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-20, 22-24, 85 and 86 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the radiopharmaceutical ¹³¹I-labeled anti-B1 antibody, does not reasonably provide enablement for any other radiopharmaceutical. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant invention is drawn to establishing a patient-specific optimally effective therapeutic dose for administration of a radiopharmaceutical which involves determining a patient's maximum effective mass (MEM). The MEM is a multiple of a calculated lean body mass determined from empirical data gathered from dose escalation studies which used ¹³¹I-labeled anti-B1 antibody. The multiple was determined to be 1.37. The specification does not describe the use of any other radiopharmaceutical. One of skill in the art would not know how to determine the multiple for another radiopharmaceutical based upon the teachings of the current specification and thus the MEM could not be calculated. It is not shown that the multiple of 1.37 as applied to ¹³¹I-labeled anti-B1 antibody dose data is also applicable to any other radiopharmaceutical. A determination of such would be undue experimentation and thus the claims are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1, 2, 4-20, 22-24, and 83-86 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “determining activity hours”. It is unclear what “activity hours” means in the claim. Activity hours could be clearance rate of the radiopharmaceutical, half-life, or hours in active form. The specification provides an example of activity hours at page 14 however this limitation is not present in the claim. Clarification is requested.

Claim 4 recites “maximum effective mass is correlated to lean body mass”. The specification indicates that the MEM is derived from lean body mass, rather than correlated to lean body mass. Clarification is requested.

Claim 9 recites “wherein the clearance profile provides an indication of the number of exponential terms in the function”. There is insufficient antecedent basis for “the function” in the claim. Further, it is unclear how exponential terms define a pattern of clearance, as this is not described in the specification.

Claim 10 recites “determining 37% injected activity”. The claim outlines plotting time points verses percent-injected activity. The claim language would make more sense by reciting “determining the time at 37% injected activity”.

Claim 13 recites “solving in the following equation”. This is unclear in that typically an equation is solved for something. In the instant case the claim might read “solving for residence time by the following equation”. Clarification is requested.

Claim 20 recites “the sum of electron energy and photon energy”. It is unclear how this sum is measured. What is the definition of the term “ Φ^{TB} ” in the equation. Clarification is requested.

Claim 20 recites “to obtain a value”. It is unclear for what a value is obtained. A therapeutic dose is established by dividing activity hours by patient-specific residence time. Does the value represent the therapeutic dose?

Claim 22 recites “number of exponential terms”. It is unclear where the exponential terms are derived. See the rejection for claim 9 above.

Claim 22 is unclear in that it recites intercepts and slopes. However, nothing has been graphed in the claim. Where is the α_i derived?

It is unclear in claim 84 if applicant intends the claim to be limited to a dose or to the ^{131}I -labeled anti-B1 antibody product. See 35 USC 101 rejection above. Clarification is requested.

Claim 85 is unclear for reciting “would belong”. Applicant is reminded to use the present tense in claim language. In this case the claim should read “patient belongs”. Appropriate correction is requested.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran
5/17/04

May 14, 2004

Lori A. Clow, Ph.D.

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Lori A. Clow